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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,844	08/10/2000	Nicholas L. Abbott	2307Z-085820US	7090

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EXAMINER

CELSA, BENNETT M

ART UNIT PAPER NUMBER

1639

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/637,844

Applicant(s)

ABBOTT ET AL.

Examiner

Bennett Celsa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-89, 109-111, 113 and 118-125 is/are pending in the application.
- 4a) Of the above claim(s) 69-89 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 109-111, 113, 118-122, 124 is/are allowed.
- 6) ☒ Claim(s) 66-68 and 123 is/are rejected.
- 7) ☒ Claim(s) 125 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Applicant's amendment dated October 30, 2003 is herein acknowledged.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

Claims 66-89 and 109-111, 113, 118-125 are currently pending.

Claims 69-89 are withdrawn from consideration as being directed to a nonelected invention.

Claims 66-68 and 109-111, 113 and 118-125 are under consideration.

Election/Restriction

2. Applicant's election without traverse of Group I (claims 66-75 and 109-113) in Paper No. 6 is acknowledged. Accordingly, claims 76-89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

3. Applicant's further election of species of :

- a. Carboxylic acid (as category A "recognition moiety");
- b. Inorganic ions (as category B "analyte"); and
- c. Ionic binding (as category C "interaction type")

in Paper No. 6 and 8, which reads on claims 66-68 and 109-117 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a))

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Accordingly, claims 69-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Withdrawn Objection (s) and/or Rejection (s)

The submission of a Katz declaration in the parent application serves to remove the Gupta (27 March 1998) thus obviating the following anticipation and obviousness rejections.

A. Claims 66-68, 109-110 and 114-115 under 35 U.S.C. 102(a) as being anticipated by Gupta et al. Science Vol. 279, (27 March 1998) pages 2077-2080;

B. Claims 66-68 and 109-115 under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. Science Vol. 279, (27 March 1998) pages 2077-2080 and Cognard, Mol. Cryst. Liq. Cryst. Vol. 1 pages 1-74(1982); and

C. Claims 66-68, 109-110 and 114-117 under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. Science Vol. 279, (27 March 1998) pages 2077-2080 and Frey et al., Anal. Chem. Vol. 68 (1996) pages 3187-3193.

Applicant's cancellation of claims 114 and 115 has overcome the obviousness rejections of:

a. claims 66-68 and 123 under 35 U.S.C. 103(a) as being unpatentable over Drawhorn and Abbott J. Phys. Chem. Vol. 99 (1995) pages 16511-515 and Evans et al. Faraday Discuss. Vol. 104 (1996) pages 37-48.

b. claims 66-68, 109-111 and 114-115 under 35 U.S.C. 103(a) as being unpatentable over Drawhorn and Abbott (1995) and Evans et al. (1996) as applied to claims 66-68, 109-110 and 114-115 above, and further in view of Cognard, Mol. Cryst. Liq. Cryst. Vol. 1 pages 1-74(1982). c. claims 66-68, 109-

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110 and 114-117 under 35 U.S.C. 103(a) as being unpatentable over Drawhorn and Abbott (1995) and Evans et al. (1996) as applied to claims 66-68, 109-110 and 114-115 above, and further in view of Frey et al., Anal. Chem. Vol. 68 (1996) pages 3187-3193.

Outstanding Objection(s) and/or Rejection(s)

4. Claims 66-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Matsuda et al. US Pat. No. 6,106,906 (8/00: filed 7/95).

Matsuda et al. teaches a display apparatus comprising a liquid crystal comprising an alignment film on at least one of two opposing substrates wherein the alignment film comprises an "organic layer" comprising a "carboxylic acid" or an "organometallic" compound with displaceable ligands (e.g. a first recognition moiety") ionically interacting with an "inorganic ion" (e.g. metals: see col. 6-8) with the later formation of a "polyimide" (e.g. "polymer") which is "rubbed" prior to the addition of a "mesogenic layer"(e.g. the addition of liquid crystals). See e.g. col. 2; col 11-12; examples (especially examples 8-11; examples 29-34; and fig. 2 and col. 35-36. The reference further teaches that the alignment film comprises "an electroconductive thin film"(e.g. see col. 6) which is detected upon a threshold applied voltage (E.g see col. 22) e.g. the reference teaches an apparatus for detecting an interaction between an analyte and a recognition moiety"; and a "device for detecting ionic bonding between an inorganic ion and a carboxylic acid" within the scope of the presently claimed invention. Alternatively, intended use language (E.g. "for detecting an interaction between an analyte and a recognition moiety"; "device for detecting ionic bonding between

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an inorganic ion and a carboxylic acid") in compositions claims are not given patentable weight where the prior art product meets the material composition limitations. The reference further teaches a 1st and/or 2nd surface comprising layers of Au, 11-mercaptoundecanoic acid and 4-cyano-4-pentylbiphenyl. See e.g. Fig. 1 and 2 and page 2077 (3rd column) to page 2078 (left column).

Discussion

Applicant's arguments directed to the above anticipation rejection were considered but deemed nonpersuasive for the following reasons.

Applicant argues that Matsuda does not teach a "recognition moiety detectably swich(es) from a first orientation to a second orientation, thereby transducing said interaction to said mesogenic layer, said transducing causing said mesogenic layer to register a visually detectable feature, whereby said feature is visually detected". This argument was considered but deemed nonpersuasive for the following reasons.

Applicant's arguments are not commensurate to what is presently claimed, since the present claims do not contain the "tranducing" and "visually detectable" limitations pointed to.

In any event, intended use (e.g. "for detecting an interaction between an analyte and a first recognition moiety" and language flowing therefrom referring to mesogenic switching) need not be afforded patentable weight in a composition claim. This indeed is the case here where the reference composition contains all of the presently claimed recited device components.

Accordingly, the above rejection is hereby maintained.

5. Claims 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by DD 278869 (5/16/90) and accompanying CAPLUS AN: 1991:243888 ("Conductometric biosensor for use in organic solvent")

DD 278869 disclose a biosensor comprising:

- a. A perfluorinated ethylene-propylene copolymer membrane with 2 Pt sputtered electrodes ("5" in fig 1) which corresponds to either the 1st or 2nd substrate presently claimed;
- b. A double (PTFE) membrane ("3" and "4" in fig. 1) which corresponds to either the 2nd or 1st substrate presently claimed;
- c. A lyotropic mesogenic layer (.1-.2mm thick) in between the 1st and 2nd substrates.

The reference further teaches an "organic" (e.g. PTFE) sensory membrane (e.g. "2b") which

is attached to the 1st and/or 2nd substrate within the scope of the present invention in which this organic sensory membrane layer "comprises" a "1st recognition moiety" (E.g. a lipase) via its intimate contact and incorporation of the liquid mesogenic layer which comprises the lipase.

The reference further teaches the "interaction" via an "opening of the reference biosensor) of the "recognition moiety" (e.g. the lipase) with the "analyte" (e.g. the triglyceride) (e.g. enzyme-substrate interaction: resulting in reversible reaction at bottom of page 2 of DD 278869) .

Discussion

Applicant's amendment and arguments directed to the above anticipation rejection were considered but deemed nonpersuasive for the following reasons. Initially, it is noted that the above rejection was modified to remove claims 109-110 in response to applicant's amendment and argument thereon.

Applicant argues that the DD 278869 reference fails to disclose that the "mesogens undergo a detectable switch in orientation". Applicant further argues that the reference uses their apparatus differently (e.g. Spohn detects the hydrolyzed analyte in the mesogenic layer not the shift in mesogenic orientation in the mesogenic layer). These arguments were considered but deemed nonpersuasive for the following reasons.

Initially, it is noted that intended use (e.g. "for detecting an interaction between an analyte and a first recognition moiety" and language flowing therefrom referring to mesogenic switching) need not be afforded patentable weight in a composition claim. This indeed is the case here where the reference compositions contains all of the presently claimed recited device components. Accordingly, under this basis alone the Spohn reference is clearly anticipatory.

Additionally, in the present instance, the reference device indeed meets applicant's claimed intended use. The above reference clearly teaches that "hydrolysis of the triglyceride to fatty acids increased the cond. (e.g. conductance) of the mesophase in a concn.-dependent manner" which permitted detection via conductance upon interaction" via an "opening of the reference biosensor) of the "recognition moiety" (e.g. the lipase) with the "analyte" (e.g. the triglyceride) (e.g. enzyme-substrate interaction: resulting in reversible

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reaction at bottom of page 2 of DD 278869). Accordingly, the reference clearly teaches a mesogenic change in orientation upon interaction between the reference recognition moiety and the analyte which permits detection. Applicant further admits that the Spohn reference "does teach that the mesogens in its mesogenic layer are capable of producing a detectable shift in orientation". E.g. see Applicant's amendment dated Oct. 30, 2003 page 13 of 28. In this respect, the Examiner lacks the facilities to test the reference device to see if it meets functional limitations (e.g. "mesogens undergo a **detectable** switch in orientation upon interaction between said first recognition moiety and said analyte" ; thus placing the burden directly on applicant (e.g. See *In re Brown*, 173 USPQ 685,688 (CCPA 1972)). In any event, it is again noted that "intended use limitations" need not be afforded any patentable weight.

Accordingly, the above rejection is hereby maintained.

6. Claims 66-68 and 123 are rejected under 35 U.S.C. 102(b) as being anticipated by Drawhorn and Abbott J. Phys. Chem. Vol. 99 (1995) pages 16511-515.

Drawhorn and Abbott teach in their Figure 1 the following: (a) two glass substrates with surfaces that are aligned such that they oppose each other, (b) a metal film (Ti) that is attached to the glass, (c) a film of permeable gold that coats the Ti layer, (d) the gold is 100 angstroms (i.e. 10 nanometers) thick, (e) equivalent organic layers (SAM's) that coat each of the gold film layers, (f) the SAM's (e.g. organosulfur) have the same recognition moieties (e.g. an alkyl i.e. CH₃ or CH₃(CH₂)₁₅) or and (g) a mesogenic layer comprised either of 5CB

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(e.g. 4 cyano 4 pentylbiphenyl) or MBBA. It is noted that an alkyl group meets the claimed structure (e.g. no structure is given) of a "recognition moiety" which is capable of interacting with a given analyte; or alternatively it is noted that intended use language (E.g. "for detecting an interaction between an analyte and a recognition moiety"; "interacting with an analyte"; "device for detecting ionic bonding between an inorganic ion and a carboxylic acid") in compositions claims are not given patentable weight where the prior art product meets the material composition limitations.

Discussion

Applicant's arguments directed to the above anticipation rejection were considered but deemed nonpersuasive for the following reasons.

Applicant argues that Drawhorn fails to explicitly teach "a mesogenic shift upon interaction between a first recognition moiety and an analyte" nor is such a shift "inherent".

This argument was considered but deemed nonpersuasive for the following reasons.

Intended use language in a composition/compound claim need not be given patentable weight. The reference device is within the scope of the presently claimed invention device.

Intended use language e.g. use in "detecting an interaction between an analyte" and applicant's mechanistic means of performing the intended use (e.g. "mesogens undergo a detectable switch in orientation upon interaction") does NOT REMOVE THE REFERENCE DEVICE FROM READING ON APPLICANTS

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DEVICE. You cannot patent old compounds(or devices) to which you discover new uses or mechanisms resulting to the use therefrom.

Accordingly, the above rejection is hereby maintained.

Allowable Subject Matter

7. Claims 109-111, 113, 118-122 and 124 are allowable over the prior art of record.

8. Claim 125 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

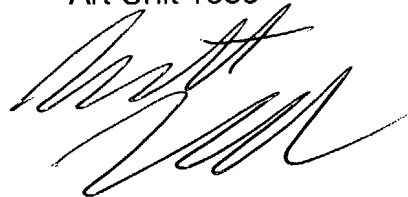
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 703-305-7556. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bennett Celsa
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Bennett Celsa', written over the printed name and title.

BC
January 28, 2004